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10/574,133	11/13/2006	Siddhartha Sikdar	UNIV0350	7922

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LAW OFFICES OF RONALD M ANDERSON
600 108TH AVE, NE
SUITE 507
BELLEVUE, WA 98004

EXAMINER	
BRUTUS, JOEL F	
ART UNIT	PAPER NUMBER
3768	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,133	SIKDAR ET AL.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 19-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 19, the terms “naturally occurring” and “not induced by an external device” are not are supported in the disclosure.

Regarding claims 20-39, they are rejected because they depend on a rejected claim for the same reason as set forth by the above.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 19-28 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (US Pat: 5,919,139) in view of Bench (US Pat: 5,951,476).

Regarding claim 19, Lin teaches a system for performing vibrational Doppler ultrasonic imaging that is pertinent to the claimed invention. Lin teaches a vibrational wave of a first frequency is introduced into an area of a subject to be scanned with the use of a transducer [see column 1 lines 16-24]. Lin teaches in FIG. an imaging system 100 that comprises a probe 101, which is typically a multi-element array of piezoelectric elements which both send and receive ultrasound signals when examining a subject, such as a living patient. Probe 101 is coupled via signal path 110 to transmitter/receiver circuitry which is coupled to a control unit 109 via bus [see column 3 lines 40-56]. Lin teaches a variable frequency [see column 2 lines 32-34].

Lin doesn't exactly teach detecting internal bleeding.

Applicant discloses when internal bleeding is present; the tissue vibrates with a frequency from a few tens to hundred Hz [see 0003, specification] and naturally occurring vibrations such as cardiac pulsation and breathing, occurs at 1 Hz or less [see 0037]. Applicant also discloses the tissue vibration processor decomposes motion and picks frequency higher than cardiac pulsation [see 0033, specification] to determine internal bleeding. Further teaches the vibration processor uses one of the following to decompose motion: auto regressive model, complex exponential, phase decomposition and Eigen decomposition based spectral analysis.

However, Lin teaches a motion discriminator circuit 608 includes separate units that extract different parameters of motion and includes velocity estimator 610, amplitude estimator 612, and variance estimator 614. Velocity estimator 610 extracts only the frequency shift component of the tissue motion, while amplitude estimator 612 extracts only the amplitude of the tissue motion [see column 9 lines 12-23].

Lin teaches whenever a frequency shift is detected above a given threshold magnitude (e.g., by a high-pass filter generally set just above the low-frequency noise floor) motion is detected [see column 5 lines 23-39]. The teaching of Lin would be able to detect internal bleeding because it discloses vibrational properties of tissue and internal structures of tissue etc... can be determining [see column 2 lines 21-30].

Nevertheless, Bench provides a method for detecting brain micro-hemorrhage (which is internal bleeding, emphasis added) by projecting bursts of ultrasound into one or both of the temples of the cranium, or into the medulla oblongata, with the readout of echoes received from different depths of tissue displayed on a screen. The readouts of the echoes indicated accrued micro shifts of the brain tissue relative to the cranium [see abstract].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to Combine Lin with Bench by using the system of Lin to detect internal bleeding; for the purpose of diagnosing hemorrhages in order to prescribe the best possible treatment.

Regarding claims 20-23, and 35-39, all other limitations are taught as set forth by the above teaching.

Lin teaches a transducer includes an audio speaker and is connected to a variable frequency tone generator that produces audio waveforms which are converted to vibrational energy by the speaker. An ultrasonic color Doppler imaging system connected to the ultrasound transducer processes the received imaging data from the ultrasound probe for display on a video monitor. The imaging system combines amplitude and variance data to generate a signal indicative of the magnitude and frequency variability of the vibrations induced by the audio transducer [see column 2 lines 32-46].

Lin teaches data are mapped according to a gray or color scale into two-dimensional image space [see column 4 lines 62-67 and column 5 lines 1-10]. Color flow processor [see fig 1]; B scan image [see column 1 lines 16-24] and color scan [see fig 7]. A location of the vibration would determine based on the image and mapping gray scale and therefore localizing the bleeding site (emphasis added).

Regarding claim 24, all other limitations are taught as set forth by the above teaching.

Lin teaches the vibrational wave is of a sufficient frequency and amplitude to induce palpable vibrations in the tissue medium of the area being scanned [see column 2 lines 21-30 and fig 3].

Regarding claims 25-26, all other limitations are taught as set forth by the above teaching.

Lin further teaches the may be implemented in discrete hardware components or, alternatively, in programmed processing units such as digital signal processors using software which is compiled, linked and then loaded from disk-based storage for execution during run-time [see column 3 lines 32-38].

Various programs containing the methods employed in these embodiments may also reside in firmware or other similar nonvolatile storage means [see column 3 lines 32-38].

Regarding claims 28 and 33-34, all other limitations are taught as set forth by the above teaching.

Lin teaches whenever a frequency shift is detected above a given threshold magnitude (e.g., by a high-pass filter generally set just above the low-frequency noise floor) motion is detected [see column 5 lines 23-39].

With regards to frequency range of tissue vibrations corresponding to bleeding at the site; Applicant discloses when internal bleeding is present the tissue vibrates with a frequency from a few tens to hundred Hz [see 0003, specification] and naturally occurring vibrations such as cardiac pulsation and breathing, occurs at 1 Hz or less [see 0037].

As disclosed here by Lin, an artisan can set the filter to a threshold above the cardiac pulsation and breathing which corresponding to noise or clutter and allow

frequencies in the range of few tens to hundred of Hz which correspond to internal bleeding (emphasis added).

Regarding claim 27, all other limitations are taught as set forth by the above teaching.

Lin doesn't teach determining bleeding rate from frequency and amplitude of tissue vibrations.

However, Lin Doppler signal processing detects frequency shifts in the returning echoes from moving acoustic reflectors within each volume element of the medium. Because frequency shifts alternate between positive and negative Doppler shifts at the rate of vibration, the temporally-averaged frequency shift signal cancels itself out, leaving only noise. However, the amplitude and variance signals are measures of the fractional volume of acoustic reflectors exceeding the given threshold Doppler shift and the range of variability [see column 5 lines 23-39].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to modify the Lin reference by determining a bleeding rate; in order to determine how intense the bleeding is occurring; thereby allowing medical parishioners to provide necessary treatment quicker.

Response to Arguments

5. Applicant's arguments with respect to claims 19-39 have been considered but are moot in view of the new ground(s) of rejection.

The objection to claim 19 is moot and the objection to claims 29-32 of the previous office is also withdrawn due to the amendment of claim 19 and the claims 29-32 are now rejected as disclosed above under 112.

Applicant argues that sound caused by vibrations (bruits) are sometimes audible using a stethoscope or palpable at the skin surface and are indicative of internal bleeding.

Lin teaches the vibrational wave is of a sufficient frequency and amplitude to induce palpable vibrations in the tissue medium of the area being scanned [see column 2 lines 21-30 and fig 3].

Response to arguments that are directed to internal bleeding can be found above with the Bench reference.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768